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SUBJECT: Taiwan Pharma: Slower Approvals, Lower Prices

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Summary

1.(SBU) A slow and complex drug approval and pricing process in Taiwan limits drug choices for patients and reduces potential profits for U.S. pharmaceutical firms. New drugs are often not available in Taiwan until more than two years after the drug has been available in the United States. Taiwan reimbursement prices are falling so much that a number of U.S. and other foreign original-drug manufacturers have pulled drugs off the market. To make matters worse, other countries are beginning to reference Taiwan's low reimbursement prices when setting drug-reimbursement prices in their own healthcare systems, magnifying the potential for increased losses for U.S. firms. Representatives of foreign pharmaceutical firms point to inadequate funding for the national health insurance system as the fundamental problem with pharmaceutical prices, but are pessimistic that the authorities will raise healthcare budgets anytime soon. Taiwan's healthcare system has a cumulative USD 1.6-billion deficit. Taiwan's Department of Health estimates this deficit could reach USD four billion by 2015, while our pharmaceutical-industry contacts estimate it will increase to USD six billion by 2012. End summary.

Three-step Process Slows Time to Market

12. (SBU) Introducing a new drug--or adding new medical use for an already-approved drug--to Taiwan's National Health Insurance (NHI) reimbursement list is a lengthy three-step process. First, the Center for Drug Evaluations (CDE), a quasi-official committee that reports to the Department of Health (DOH) Bureau of Pharmaceutical Affairs (BOPA), must evaluate the safety and efficacy of the drug, and pass its recommendation to BOPA. U.S. drug companies tell us that, even under the faster track for drugs already approved by the U.S. FDA, the CDE takes two to three months from the time of application to begin consideration of a new drug, after which the CDE will usually need several more meetings over another two to three months to review the new drug's clinical trial results and other data. During this process, the CDE often asks drug companies for more information on some aspect of the drug's safety or efficacy, slowing the process further. After the CDE passes its recommendation to BOPA's approval committee, BOPA reviews the CDE decision, and often asks companies for further information before finally granting approval for the drug's use in Taiwan. Finally, the DOH Bureau of National Health Insurance (BNHI) then takes about

six months to evaluate and assign a reimbursement price to the drug.

13. (SBU) According to original-drug manufacturers, the problem is not only the sluggishness of the approval process, but also the process' unpredictability. Our contacts tell us that they cannot anticipate what sorts of data or other trial information the CDE or BOPA's committee will ask for, nor can drug-makers reliably predict how long it will take either to make a decision. Peter Wang, President and Managing Director of Wyeth Taiwan, complained recently to econoff that "policy seems to change day by day." Wang said the CDE or BOPA will reject a drug for a myriad of often-unpredictable reasons, and each agency will often ask for further information or additional trials, slowing down the approval process by two to three months with each request.

14. (SBU) Original-drug manufacturers in Taiwan also claim that the authorities have become less willing to accept drug-trial results and other documentation from outside Taiwan. For example, for drugs manufactured in Europe, Taiwan formerly accepted a certificate of approval from either E.U. or U.S. regulatory authorities in order to fast-track the drug for domestic use. Taiwan, however, now requires certification from both, which usually results in a delay while the company waits for the approval process to finish in the United States. Je Hwa Park, Managing Director for Janssen-Cilag (JC) Taiwan, recently told us that in the past, Taiwan's drug-approval authorities waived bridging studies--supplemental studies performed in Taiwan to provide clinical data on the efficacy, safety, and dosage specifically for the Taiwan market--for about 85 percent of all drugs, but that this has fallen to 45 percent since 2004. Sometimes, even a bridging study is not enough. According to Park, in one recent case, the CDE required JC to re-start the testing and trial process for a new anti-cancer drug, while the Korean regulatory authorities asked only for a bridging study for the same drug.

15. (SBU) BOPA Director General Chi-chou Liao, however, recently told
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econoff that the agency's licensing and approval process has not gotten any slower for most new drugs, nor did he think that BOPA has significantly increased requests for supplemental studies. Liao did comment, however, that BOPA has become more aware in recent years that the effectiveness of some drugs changes due to ethnic differences between people in Taiwan and the test subjects of most clinical studies done outside of Taiwan. For example, Liao noted, BOPA has found that a lung cancer drug that was withdrawn from the U.S. market as ineffective is in fact very effective for Taiwanese lung cancer patients. Due to cases such as this, BOPA will sometimes ask for additional studies that include Taiwanese or Chinese patients.

16. (SBU) After the CDE and BOPA approve a drug for use in Taiwan, BNHI begins the process of assigning a reimbursement price for the drug. Although BNHI usually takes about six months to assign a price, original drug manufacturers say that the initial price is usually much lower than the median price in the group of 10 advanced economies (A10) that the pharmaceutical industry uses as a worldwide price benchmark, which comprises the United States, Canada, Australia, New Zealand, France, Germany, Italy, Sweden, Switzerland, and Belgium. Since the initial price is usually lower than what the companies are willing to accept, in most cases they appeal the BNHI decision, setting the six-month process in motion again, and prolonging the pricing process to one year. In a recent meeting with econoff, BNHI Vice President Cheng-hua put the blame for long price-assignment processes on drug companies for appealing "again and again" for higher prices after BNHI has set an initial price. Lee noted that tight BNHI budgets have forced the agency to set initial prices that are in many cases lower than what drug firms expect, but added that most new drugs introduced into Taiwan are not "breakthrough" drugs, and that drug companies should therefore not expect prices for such drugs to be close to the A10 average.

17. (SBU) Chang Ly-yun, Chairwoman of Taiwan's only NGO focusing on overall healthcare reform, the Taiwan Health Reform Foundation (THRF), told econoff on April 17 that tight BNHI budgets have indeed

prompted the Bureau to set low initial drug prices. She blamed the budget woes on both inadequate funding for the Taiwan healthcare system, as well as BNHI's failure to remove older, less-effective pharmaceuticals from its 10,000-drug reimbursement list. Continuing to reimburse hospitals for dispensing older drugs, she maintains, saps money that could be available to pay more for newer, more effective medicines. Chang suggested hospitals may be prescribing these older medicines less for their medical effectiveness and more out of either habit, or in order to raise hospital revenues from the difference between the lower prices hospitals have negotiated with drug companies and the higher amounts that BNHI reimburses for the same drugs.

18. (SBU) In any case, according to drug-industry figures, the average time for the approval plus pricing processes has increased to at least two years from an average of one year earlier this decade. Wyeth's Wang said that, in his company's experience, getting a drug to market in Taiwan now takes from two to 2.5 years. Janssen-Cilag's Park recently told econoff that, due to slower approvals and pricing times, JC launches new products in Taiwan from one to two years behind South Korea, where he says approvals have sped up over the past two years. Park blames both BNHI for what he characterizes as its slow and unsatisfactory pricing decisions, as well as the separate--and sometimes conflicting--review processes at BOPA and CDE. He accused BOPA and CDE bureaucrats of creating new, ad-hoc approval hurdles to increase their agency's power and prove how "patriotic" they are by "linking approval to reducing the financial burden on the healthcare system instead of healthcare need." This translates to a situation where, in many cases, Taiwan patients must wait two or more years after the drugs have been approved for the U.S. market.

Low Prices Reducing Market's Appeal

19. (SBU) Original-drug manufacturers' difficulties don't end when they finally get a BNHI reimbursement rate for a new drug, since the initial price is, in most cases, continually reduced by BNHI's biannual price-volume surveys (PVSSs). Since individual hospitals negotiate drug prices directly with drug companies, BNHI conducts PVSSs to ascertain the average price that Taiwan's hospitals are paying for each drug, and then adjusts the reimbursement rate. After each PVS, hospitals typically re-negotiate contracts with drug companies in order to push the price down again, since hospitals rely heavily on revenues derived from the difference between the prices they have negotiated with drug companies and the higher amounts that BNHI reimburses for the same drugs--the source of the

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so-called "Black Hole" in Taiwan's pharmaceuticals budget (reftel).

110. (SBU) The result of this continual downward price pressure is that, according to estimates by original-pharmaceutical manufacturers, average prices for on-patent drugs in Taiwan are 40 percent below the A10 median. According to Jordan Ter, Managing Director for Merck, Sharpe and Dohme Taiwan (MSD), low profits for original-drug manufacturers have reduced Taiwan from one of the region's most attractive markets to one of the least over the past five years. MSD and other drug makers tell us that their projections show Taiwan will be the lowest-growth market for original drugs in East Asia over the next five years.

111. (SBU) Ter is also pessimistic about the long-term market for original-drug makers in Taiwan. He recently told econoff that Taiwan is less and less important to MSD headquarters, which focuses instead on other regional markets such as Japan, China, and, increasingly, South Korea, which he says offers both a larger market and a better business and R&D environment. He hopes that Taiwan will become an easier place for drug companies to do business after a new administration takes office in May, but for now he is worried that his headquarters' recent trend of reducing both sales and research funding in the Taiwan market will continue.

112. (SBU) According to Janssen-Cilag's Park, Singapore, Korea, Thailand, and China are now competitive with Taiwan in drug trials,

and since his company's funding for trials tends to correlate with sales, he believes that the company will continue a relative shift of spending on research and trials into other markets. Park said although absolute investment in the Taiwan market has been steady over the past few years, the company's investment in Taiwan relative to other regional markets is less than it should be considering Taiwan's research capabilities.

¶13. (SBU) David Lin, Country Manager for Pfizer Taiwan, told econoff recently that slowing sales have caused a two-year decline in the company's business in Taiwan. However, Lin said Pfizer--unlike other foreign drug makers in Taiwan--separates its view of a market's sales potential from decisions on where to invest its research and testing dollars. According to Lin, Pfizer continues to increase testing and research spending in Taiwan due to the high quality of Taiwan's research hospitals and universities.

Low Prices Pushing Drugs Out of Market

¶14. (SBU) Taiwan's low reimbursement rates are not just hurting companies' sales figures, but are also driving drugs out of the domestic market. In some cases, successive price-volume surveys reduce the BNHI reimbursement price to such a low level that pharmaceutical companies stop selling the drug in Taiwan. According to Ter, MSD has already pulled several drugs from the Taiwan market. MSD has pulled drugs from other markets in the region as well--including New Zealand--and Ter said that the company will not hesitate to continue doing so in any market where the price drops below cost. According to David Lin, in 2007 alone, Pfizer stopped selling 10 of its total Taiwan line of 90 drugs for this reason. Janssen-Cilag and Wyeth also both told us that they have dropped products from the Taiwan market for the same reason.

¶15. (SBU) Sometimes the difference between Taiwan's reimbursement price and the international market price can put firms in an awkward position of considering pulling potentially life-saving drugs from the market. In the case of the Pfizer product Solu-cortef, which is used in ambulances and emergency rooms for treating acute tuberculosis and severe allergic reactions, the company decided in early 2007 to remove the drug from the Taiwan market after the last PVS reduced the BNHI reimbursement price to 28 NT/vial, well below the international market price of 130 NT/vial. The company decided to phase the drug out over 2007 in order to give customers time to adjust. In December 2007, however, hospitals notified Pfizer that the drug is "essential" and cannot be supplied by local generic-drug manufacturers, and asked the company to continue selling the drug in Taiwan. Pfizer then notified BNHI that the company will not be able to supply Solu-cortef to Taiwan unless BNHI moves quickly to re-adjust its reimbursement price to at least 75 NT/vial. BNHI, however, has not moved to expedite the price review, meaning that the Bureau will not start consideration of this price readjustment until late April, with a final decision unlikely until August. Pfizer has not decided what to do, but told econoff that if BNHI does take until summer to decide, Pfizer will stop selling the drug in Taiwan.

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Defensive Moves to Drop Drugs from Market

¶16. (SBU) Foreign drug companies in Taiwan also express concern that countries in the region are starting to reference BNHI's reimbursement prices when setting drug-reimbursement prices in their own healthcare systems. According to several companies' representatives, in 2007, Korea started to set Taiwan reimbursement prices as target prices for original-drug manufacturers' products in Korea. Wyeth's Wang said that China and Thailand were also starting to reference Taiwan's prices--which are both attractively low and also clearly posted on the BNHI website--when determining their own domestic drug prices. Wang warned that if this continues, Wyeth would consider removing drugs from the Taiwan market--even profitable ones--as a defensive measure to avoid losing money in other markets. JC's Park said that the company has already pulled products out of Taiwan for this reason, and echoed Wyeth's concerns

about other countries using Taiwan's reimbursement prices to set prices in their own markets.

Low Healthcare Budget Is Root of Problem

¶17. (SBU) Representatives of foreign pharmaceutical firms all point to inadequate funding for national healthcare as the fundamental problem with BNHI pharmaceutical pricing. According to healthcare experts in Taiwan, per-capita monthly premiums and visit co-pays are roughly half of those in South Korea, which has a national health-insurance system of similar scope and age as Taiwan's (reftel). As a result, Taiwan's National Healthcare Insurance (NHI) system has a cumulative deficit of USD 1.6-billion. Our pharmaceutical-industry contacts estimate this figure will increase to USD six billion by 2012, and BNHI itself estimated in 2005 that the NHI deficit would reach USD four billion by 2015 if premiums are not raised. Because of the healthcare system's budget woes, both public and private hospitals are severely underfunded, and therefore make up shortfalls in the difference between the lower prices they have negotiated with drug companies and the higher amounts that BNHI reimburses them for the same drugs. According to BOPA Director General Chi-chou Liao, hospitals derive up to half of their operating profits from this difference. To ensure that this price gap remains as high as possible, hospitals--which are by far the drug companies' largest customers in Taiwan--constantly negotiate with drug companies to push prices down.

¶18. (SBU) Wyeth's Wang believes that, due to Taiwan's relatively low healthcare spending, delaying the next PVS or implementing standard contracts for all hospitals would provide only temporary relief to original-drug manufacturers. JC's Park agrees that implementing mandatory standard contracts will not make a difference as long as the budget does not grow, and told econoff that the only long-term solution is either to cut back on healthcare services or persuade the Taiwan public that it will need to pay more to enjoy the current level of health care.

¶19. (SBU) Most of our private-sector interlocutors, however, are pessimistic that Taiwan's leaders have the political will to make such efforts. Instead, they project that in the short and medium terms, BNHI will continue to try to control costs by reducing reimbursement prices for original drugs, and hospitals will continue to re-negotiate drug prices whenever this happens. Although Pfizer's Lin thinks policymakers and voters in Taiwan are smart enough to fix the budget problem before a true crisis arrives, he worries electoral pressures will continue to put the fear of rate hikes into the average politician and bureaucrat. JC's Park sounded the only note of optimism among the U.S. firms, recently telling econoff he believes that 2008 in Taiwan could be the year voters decide that without an increase in funding and a decrease in some coverage, the healthcare system will begin to falter.

Comment

¶20. (SBU) Taiwan's National Health Insurance system is hugely popular and provides a relatively high level of care at low prices to virtually everyone in Taiwan. Unfortunately the system is not sustainable at current funding levels, it delays access to the newest medicines, and greatly reduces potential profits for U.S. firms. The United States may want to widen the topics discussed under TIFA pharma working groups to include ways to speed up pharmaceutical approvals in Taiwan. We will be engaging with the CDE, BOPA, and BNHI over the near future to express our concerns about the drug approval and pricing process. As for increasing BNHI spending on drugs, foreign pharmaceutical firms may have domestic

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allies in doctors and the hospitals that they work for, which form the most powerful domestic medical interest group (see reftel for more information). End comment.